

Minutes of Meeting
Alabama Medicaid Agency
Pharmacy and Therapeutics Committee

August 7, 2019

Members Present: Dr. Lee Carter (Chair), Dr. Kimberly Graham, Dr. Frances Heinze (Vice-chair), Dr. Peter Julian Hughes, Dr. Kelli Newman, Dr. Melinda Rowe, Dr. Robert Smith, and Dr. Amanda Williams

Members Absent: Dr. Elizabeth Dawson and Dr. Ramakanth Vemuluri

Health Home Pharmacists Present via Teleconference: Allana Alexander, Amy Donaldson, Joshua Lee, Angela Lowe, Debbie Mulanix, Lacey Nelson, Lydia Rather, Kristian Testerman, and Lauren Ward

Presenters: Dr. Rachel Bacon

1. OPENING REMARKS

Chairperson Carter called the Pharmacy and Therapeutics (P&T) Committee Meeting to order at 9:09 a.m.

2. APPROVAL OF MINUTES

Chairperson Carter asked if there were any corrections to the minutes from the May 8, 2019 P&T Committee Meeting.

There were no objections. Dr. Hughes made a motion to approve the minutes as presented and Dr. Smith seconded to approve the minutes. The minutes were unanimously approved.

3. PHARMACY PROGRAM UPDATE

Dr. Newman stated that new CMS guidance for implementation of the new Medicaid DUR provisions included in the SUPPORT Act will be reviewed and approved by the DUR Board. These provisions are designed to reduce opioid related fraud, misuse, and abuse. The Alabama Coordinated Health Networks (ACHN) program continues to progress. The managed care management team has been completing onsite readiness reviews, and ACHN webinars are occurring. Dr. Rowe explained the programs being implemented, which is scheduled to occur on October 1, 2019.

4. ORAL PRESENTATIONS BY MANUFACTURERS/MANUFACTURERS' REPRESENTATIVES

Five-minute verbal presentations were made on behalf of pharmaceutical manufacturers. The process and timing system for the manufacturers' oral presentations were explained. The drugs and corresponding manufacturers are listed below with the appropriate therapeutic class. There were zero manufacturer verbal presentations at the meeting.

5. PHARMACOTHERAPY CLASS RE-REVIEWS (Please refer to the website for full text reviews.)

The pharmacotherapy class reviews began at approximately 9:30 a.m. There was a total of 16 drug class re-reviews. The first generation antihistamines; estrogens; alpha glucosidase inhibitors; amylinomimetics; biguanides; dipeptidyl peptidase-4 inhibitors; incretin mimetics; insulins; meglitinides; sodium-glucose cotransport 1 inhibitors; sodium-glucose cotransport 2 inhibitors; sulfonylureas; thiazolidinediones; antidiabetic agents, miscellaneous; prenatal vitamins; and immunomodulatory agents used to treat multiple sclerosis were all last reviewed in May 2017. There was one new drug class review: the antigout agents.

First Generation Antihistamines: Ethanolamine Derivatives, AHFS 040404; Ethylenediamine Derivatives AHFS 040408; and Propylamine Derivatives AHFS 040420

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the first generation antihistamines included for this review are listed in Table 1 on page 9. The first generation antihistamines are approved for use in several allergic and nonallergic conditions; however, these agents are primarily utilized for the treatment of allergic rhinitis, urticaria, and angioedema. The eye, ear, nose and throat anti-allergic agents (American Hospital Formulary Service 520200) were previously reviewed and not included in this review. The majority of these agents are available in a generic formulation. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed. Dexchlorpheniramine (Ryclora[®]) has been included in the packet since the last review.

There is insufficient evidence to support that one brand first generation antihistamine is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand first generation antihistamine is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Estrogens: AHFS 681604

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the estrogens that are included in this review are listed in Table 1 on page 75. Estradiol, estradiol valerate, estradiol-norethindrone, and norethindrone-ethinyl estradiol are available in a generic formulation. Enjuvia® (estrogens, conjugated synthetic B) and estropipate have been discontinued since the last review. The estrogens are approved for the treatment of vasomotor symptoms associated with menopause, vulvar and vaginal atrophy, abnormal uterine bleeding, hypoestrogenism, prevention of postmenopausal osteoporosis, as well as for the palliative treatment of prostate and breast cancer. They are available in a variety of dosage forms, including injectable, oral, topical, transdermal, and vaginal preparations. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

There is insufficient evidence to support that one brand estrogen is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand estrogen is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Alpha Glucosidase Inhibitors: AHFS 682002

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the alpha-glucosidase inhibitors are approved for use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The alpha-glucosidase inhibitors that are included in this review are listed in Table 1 on page 181. Acarbose and miglitol are available in a generic formulation. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

There is insufficient evidence to support that one brand alpha-glucosidase inhibitor is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand alpha-glucosidase inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Amylinomimetics: AHFS 682003

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that pramlintide is the only amylinomimetic agent currently available. It is approved for use as an adjunctive treatment in patients with type 1 and type 2 diabetes mellitus who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy. Amylin is co-secreted with insulin by pancreatic beta cells in response to food intake. It affects postprandial glucose levels by slowing gastric emptying, suppressing glucagon secretion, and regulating food intake via modulation of appetite. Pramlintide is a synthetic analog of human amylin. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

There is insufficient evidence to support that one brand amylinomimetic is safer or more efficacious than another within its given indication. Since pramlintide is only approved for use as an adjunctive treatment in patients with type 1 and type 2 diabetes mellitus, it should be managed through the existing medical justification portion of the prior authorization process.

Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand amylinomimetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Biguanides: AHFS 682004

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that metformin remains the only biguanide that is currently available, and it is FDA-approved for use as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes. Metformin is available as an immediate-release tablet, extended-release tablet, and solution. Both the immediate- and extended-release tablets are available generically.

Metformin remains the recommended first-line therapy for most antidiabetic treatment regimens and remains the cornerstone to most combination dual and triple therapy regimens. Among current treatment guidelines, preference of one formulation of metformin over another is not stated.

There is insufficient evidence to support that one brand biguanide is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

All brand products within the class reviewed are comparable to each other and to the generic products in the class and offer no significant clinical advantage over other alternatives in general use.

No brand biguanide is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Dipeptidyl Peptidase-4 (DPP-4) Inhibitors: AHFS 682005

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the DPP-4 inhibitors included in this review are listed in Table 1 on page 367. Alogliptin and alogliptin combination products are available in a generic formulation; metformin and pioglitazone are also available generically in separate formulations. The DPP-4 inhibitors are approved for use as an adjunct therapy to diet and exercise to improve glycemic control in adults with type 2 diabetes. In general, all DPP-4 inhibitors fixed-dose combination products are available for use when treatment with both drug components is appropriate.

There have been postmarketing reports of serious hypersensitivity reactions in patients taking DPP-4 inhibitors. These reactions include anaphylaxis, angioedema and exfoliative skin conditions including Stevens-Johnson syndrome. There have also been postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, in patients taking DPP-4 inhibitors. A warning has also been added to the labeling of DPP-4 inhibitors to inform of the potential increased risk of heart failure in high-risk populations.

Current treatment guidelines recommend the DPP-4 inhibitors as a potential second-line treatment option to be added to or used in combination with metformin in patients not achieving glycemic control. Due to their mechanism of action, the DPP-4 inhibitors are associated with a lower rate of hypoglycemia compared to other antidiabetic agents, and they also have a well established efficacy and safety profile when used in combination with metformin. The DPP-4 inhibitors may also be a potential treatment option for initial therapy in patients who have a contraindication to metformin. Among all current treatment guidelines, preference of one DPP-4 inhibitor over another is not stated.

There is insufficient evidence to support that one brand DPP-4 inhibitor is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand DPP-4 inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Incretin Mimetics: AHFS 682006

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the incretin mimetics are FDA approved for use as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. The incretin mimetics included in this review are listed in Table 1 on page 468. Byetta® and Bydureon® contain the same active ingredient, exenatide. Bydureon® is a long-acting formulation of exenatide. There are no incretin mimetics available generically.

Since the last review, two new incretin mimetics have been approved. Adlyxin® (lixisenatide) was approved in 2016 and Ozempic® (semaglutide) was approved in 2017. Lixisenatide is structurally similar to exenatide and has a high binding affinity to GLP-1, which allows for once-daily dosing. Semaglutide is a GLP-1 analogue with 94% sequence homology to human GLP-1. The principal mechanism of protraction resulting in the long half-life of semaglutide is albumin binding, which results in decreased renal clearance and protection from metabolic degradation. Furthermore, semaglutide is stabilized against degradation by the DPP-4 enzyme. Semaglutide has an elimination half-life of approximately one week and is dosed weekly. Additionally, Victoza® (liraglutide) has been approved to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.

According to current clinical guidelines for the management of type 2 diabetes, metformin remains the cornerstone of most antidiabetic treatment regimens. At this time, uniform recommendations on the best agent to be combined with metformin cannot be made; therefore, advantages and disadvantages of specific antidiabetic agents for each patient should be considered. According to the 2019 update of the American Diabetes Association Standards of Medical Care in Diabetes and the 2018 update of the Management of Hyperglycemia in Type 2 Diabetes, in patients with type 2 diabetes who have established atherosclerotic cardiovascular disease (ASCVD), heart failure, or chronic kidney disease, choose a SGLT2 inhibitor or GLP-1 receptor agonist that has demonstrated cardiovascular disease benefit for add-on therapy with metformin.

The FDA-approval of lixisenatide was based upon the GetGoal program that included 13 trials in patients with type 2 diabetes and the cardiovascular outcomes study, Elixia. The GetGoal program established the efficacy and safety profile of lixisenatide and included trials as monotherapy and as an add-on to metformin, a sulfonylurea or pioglitazone, basal insulin or prandial insulin. A cardiovascular outcomes trial in patients with type 2 diabetes who had had a myocardial infarction or who had been hospitalized for unstable angina within the previous 180 days were randomized to either lixisenatide or placebo (N=6,068). The primary endpoint was a composite of first occurrence of death from cardiovascular causes, nonfatal myocardial infarction, nonfatal stroke, or hospitalization for unstable angina. After a median follow-up of 25 months, there was a primary end-point event occurred in 13.4% of patients in the lixisenatide group and in 13.2% in the placebo group (hazard ratio, 1.02; 95% CI, 0.89 to 1.17), which showed the noninferiority of lixisenatide to placebo ($P<0.001$) but did not show superiority ($P=0.81$). The approval of semaglutide is based on the SUSTAIN clinical trial program. In patients with type 2 diabetes, semaglutide showed reductions in HbA_{1c} compared with placebo, sitagliptin, dulaglutide and exenatide extended-release. As a secondary endpoint, treatment was associated with reductions in body weight. In addition, in a cardiovascular outcomes trial, the primary cardiovascular composite outcome occurred in 108 of 1,648 patients (6.6%) in the semaglutide group and in 146 of 1,649 patients (8.9%) in the placebo group (HR, 0.74; 95% CI, 0.58 to 0.95; $P<0.001$ for noninferiority).

Gastrointestinal-related adverse events are common with incretin mimetics. There have been postmarketing reports of acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, in patients taking these agents. There have also been postmarketing reports of altered renal function, including increased serum creatinine, renal impairment, worsened chronic renal failure, and acute renal failure, sometimes requiring hemodialysis or kidney transplantation. Patients may develop antibodies to the incretin mimetics consistent with the potentially immunogenic properties of protein and peptide pharmaceuticals.

In 2017, Victoza® (liraglutide) was approved to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease. The FDA's decision is based on the results from the LEADER trial, which was a multicentre, international, randomized, double-blind, placebo-controlled trial investigating the long-term (3.5 to 5 years) effects of liraglutide compared to placebo, both in addition to standard of care, in people with type 2 diabetes at high risk of major cardiovascular events (n=9,340). The primary composite outcome occurred in fewer patients in the liraglutide group (13.0%) than in the placebo group (14.9%; HR, 0.87; 95% CI, 0.78 to 0.97; $P<0.001$ for noninferiority; $P=0.01$ for superiority).

There is insufficient evidence to support that one brand incretin mimetic is safer or more efficacious than another within its given indication. Since the incretin mimetics are not recommended as first-line therapy for the treatment of type 2 diabetes mellitus, they should be managed through the medical justification portion of the prior authorization process. The incretin mimetics should be available for second-line treatment of patients with type 2 diabetes and atherosclerotic cardiovascular disease.

Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand incretin mimetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Insulins: AHFS 682008

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the insulins that are included in this review are listed in Table 1 on page 577. There are no generic formulations of insulin; however, there are several products available over-the-counter. Additionally, an authorized generic formulation of Humalog® (insulin lispro injection) is available.

Three new formulations and two new combination products have been approved since the last review. Fiasp® (insulin aspart injection) is a rapid-acting human insulin analog. This agent can be dosed at the beginning of a meal or within 20 minutes after starting a meal. Fiasp® is a new formulation of NovoLog® (insulin aspart) in which the addition of niacinamide (vitamin B3) helps to increase the speed of the initial insulin absorption, resulting in an onset of appearance in the blood in approximately 2.5 minutes. Basaglar® (insulin glargine) is a long-acting human insulin analog and is the first insulin product approved through an abbreviated approval pathway under the Federal Food, Drug, and Cosmetic Act 505(b)(2), based upon similarity to Lantus® (insulin glargine). It is not categorized as a biosimilar having not been approved under the 351 (k) pathway. Admelog® (insulin lispro) is a rapid-acting human insulin analog and is the first short-acting insulin approved as a “follow-on” product (submitted through the agency’s 505(b)(2) pathway). The application for Admelog® relied, in part, on the FDA’s finding of safety and effectiveness for Humalog® (insulin lispro injection) to support approval. Xultophy® (insulin degludec/liraglutide) is a combination of insulin degludec, a long-acting human insulin analog, and liraglutide, a glucagon-like peptide 1 (GLP-1) receptor agonist, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Soliqua® (insulin glargine/lixisenatide) is also a combination a long-acting human insulin analog and a GLP-1 receptor agonist and has the same indication.

In general, insulin is FDA-approved for use in type 1 and 2 diabetes. Essentially all insulin products act the same and have comparable efficacy among them; the primary differences between the products revolve around pharmacokinetic and pharmacodynamic properties. Insulin is the standard of care for patients with type 1 diabetes.

In summary, the insulin analogs have been shown to be at least as effective, or more effective, than human insulin. In several studies, there was a lower risk of hypoglycemia with the insulin analogs compared to human insulin. There is insufficient evidence to conclude that one rapid-acting insulin analog is safer or more efficacious than another. There is also insufficient evidence to conclude that one long-acting insulin analog is safer or more efficacious than another.

Therefore, all brand products within the class reviewed, with the exception of rapid-acting and long-acting insulin analogs, are comparable to each other and to the generics and over-the-counter products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use. Rapid-acting insulin analogs offer significant clinical advantages in general use over short-acting human insulin but are comparable to each other. Long-acting insulin analogs offer significant clinical advantages in general use over intermediate-acting human insulin but are comparable to each other.

No brand insulin product, with the exception of rapid- and long-acting insulin analogs, is recommended for preferred status. Alabama Medicaid should accept cost proposals to determine the most cost effective products and possibly designate one or more preferred brands. Alabama Medicaid should accept cost proposals from manufacturers so that at least one brand rapid- and long-acting insulin analog is selected as a preferred agent.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Meglitinides: AHFS 682016

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that there have been no major or clinically significant changes to the meglitinides since the last time this class was reviewed. Nateglinide and repaglinide are available in generic formulations.

The meglitinides are not consistently included as part of the general recommendations for the management of type 2 diabetes. While they can be viewed as a potential second-line treatment option to be added to or used in combination with metformin in patients not achieving glycemic goals, treatment guidelines note that meglitinides are associated with limited HbA_{1c} lowering ability, weight gain, and a greater risk of inducing hypoglycemia compared to other available antidiabetic agents. Among all current treatment guidelines, preference of one meglitinide over another is not stated. Meglitinides may also be used as a potential option for initial therapy in patients who have a contraindication to metformin. Meglitinides are noted as being useful when postprandial hypoglycemia is present.

There is insufficient evidence to support that one brand meglitinide is safer or more efficacious than another. Since the meglitinides are not recommended as first-line therapy for the treatment of type 2 diabetes, formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

All brand products within the class reviewed are comparable to each other and to the generic products in the class and offer no significant clinical advantage over other alternatives in general use.

No brand meglitinide is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Sodium-glucose Cotransport 1 Inhibitors: AHFS Class 682017

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that currently there are no prescription medications classified by AHFS as Sodium-glucose Cotransport 1 Inhibitors. No SGLT1 inhibitor is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 682017 in the Preferred Drug List screening process. If new prescription sodium-glucose cotransport 1 inhibitors are added, it is recommended that this class be re-reviewed.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Sodium-glucose Cotransport 2 Inhibitors: AHFS Class 682018

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the sodium-glucose cotransport 2 (SGLT2) inhibitors included in this review are listed in Table 1 on page 787. There are no generic products available. New agents have been included since the last review, including ertugliflozin (Steglatro[®]) and several combination products (dapagliflozin with saxagliptin, ertugliflozin with metformin, and ertugliflozin with sitagliptin), as well as an extended release formulation of empagliflozin-metformin. All SGLT2 inhibitors are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Empagliflozin is also indicated to reduce the risk of cardiovascular death, and canagliflozin to reduce the risk of major cardiovascular events, in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

According to current clinical guidelines for the management of type 2 diabetes, metformin remains the cornerstone to most antidiabetic treatment regimens. Additionally, patients with a high glycosylated hemoglobin (HbA_{1c}) will most likely require combination or triple therapy in order to

achieve glycemic goals. At this time, uniform recommendations on the best agent to be combined with metformin cannot be made; therefore, advantages and disadvantages of specific antidiabetic agents for each patient should be considered. SGLT2 inhibitors are recommended as a potential first, second, or third-line treatment option to be added as an alternative to or in combination with metformin in patients not achieving glycemic goals. SGLT2 inhibitors are acceptable therapeutic alternatives that reduce glucose without weight gain or hypoglycemia. According to the 2019 update of the American Diabetes Association Standards of Medical Care in Diabetes and the 2018 update of the Management of Hyperglycemia in Type 2 Diabetes, in patients with type 2 diabetes who have established atherosclerotic cardiovascular disease (ASCVD), heart failure, or chronic kidney disease, choose a SGLT2 inhibitor or GLP-1 receptor agonist that has demonstrated cardiovascular disease benefit for add-on therapy with metformin.

The efficacy and safety of ertugliflozin have been studied in several multicenter, randomized, double-blind, placebo- or active comparator-controlled clinical trials including subjects with type 2 diabetes. Ertugliflozin has been studied as monotherapy and in combination with metformin and/or a DPP-4 inhibitor, as well as other antidiabetic medications, including insulin and a sulfonylurea. In general, treatment with ertugliflozin reduced HbA_{1c} compared to placebo, with the exception of subjects with moderate renal impairment in the VERTIS RENAL study, in which treatment with ertugliflozin did not result in a reduction in HbA_{1c} compared to placebo.

The EMPA-REG OUTCOME trial showed that empagliflozin therapy reduced the aggregate outcome of myocardial infarction, stroke, and cardiovascular death by 14% (absolute rate 10.5 vs 12.1% in the placebo group; $P < 0.001$ for noninferiority and $P = 0.04$ for superiority), due to a 38% reduction in cardiovascular death (absolute rate 3.7 vs 5.9%). In the Canagliflozin Cardiovascular Assessment Study (CANVAS), 10,142 participants with type 2 diabetes (two-thirds with established CVD) were randomized to canagliflozin or placebo and were followed for an average 3.6 years. The mean age of patients was 63 years and 66% had a history of cardiovascular disease. Fewer participants in the canagliflozin group than in the placebo group had a primary outcome event (the composite of death from cardiovascular causes, nonfatal myocardial infarction, or nonfatal stroke): 26.9 vs. 31.5 participants with an event per 1000 patient-years (HR, 0.86; 95% CI, 0.75 to 0.97; $P < 0.001$ for noninferiority; $P = 0.02$ for superiority). Of note, there was an increased risk of lower-limb amputation with canagliflozin (6.3 vs. 3.4 participants per 1,000 patient-years; HR, 1.97; 95% CI, 1.41 to 2.75). Canagliflozin products have a boxed warning for the risk of lower limb amputation, stating that an approximately 2-fold increased risk of lower limb amputations associated with canagliflozin use was observed in CANVAS and CANVAS-R, two large, randomized, placebo-controlled trials in patients with type 2 diabetes who had established CVD or were at risk for CVD. Overall, in high-risk populations, empagliflozin and canagliflozin appear to decrease cardiovascular morbidity and mortality in patients with type 2 diabetes and overt cardiovascular disease. Dapagliflozin does not appear to reduce atherosclerotic cardiovascular morbidity or cardiovascular mortality, but similar to empagliflozin and canagliflozin, dapagliflozin reduces hospitalization for heart failure.

A variety of warnings and precautions are listed in the package inserts for the SGLT2 inhibitors, including risks for hypotension, ketoacidosis, acute kidney injury, urosepsis and pyelonephritis, hypoglycemia, Fournier's Gangrene, genital mycotic infections, hypersensitivity reactions, bone fracture, and increased LDL-C. During clinical trials, common adverse side effects associated with

the SGLT2 inhibitors included increased incidence of female genital mycotic infections, urinary tract infection, and increased urination.

There is insufficient evidence to support that one brand SGLT2 inhibitor is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process. The SGLT2 inhibitors empagliflozin and canagliflozin should be available for second-line treatment of patients with type 2 diabetes and atherosclerotic cardiovascular disease.

Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use within its given indication.

No brand sodium-glucose cotransport 2 inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Vice chairperson Cohenour asked the P&T Committee members to mark their ballots.

Sulfonylureas: AHFS 682020

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that there have been no major or clinically significant updates to the sulfonylureas since the last time this class was reviewed. The sulfonylureas are FDA-approved for use as an adjunct therapy to diet and exercise to improve glycemic control in adults with type 2 diabetes. All sulfonylureas are available in a generic formulation, including the fixed-dose combination products.

There is insufficient evidence to support that one brand sulfonylurea is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

All brand products within the class reviewed are comparable to each other and to the generic products in the class and offer no significant clinical advantage over other alternatives in general use.

No brand sulfonylurea is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Thiazolidinediones: AHFS 682028Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the thiazolidinediones that are included in this review are listed in Table 1 on page 962. Pioglitazone, pioglitazone-glimepiride, and pioglitazone-metformin are available in generic formulations. Metformin and glimepiride are also available generically in separate formulations. In December 2016, the FDA concluded that use of pioglitazone may be linked to an increased risk of bladder cancer. The labels of pioglitazone-containing medicines already contained warnings about this risk and have now been updated to describe the additional studies reviewed. There have been no other major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

There is insufficient evidence to support that one brand thiazolidinedione is safer or more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand thiazolidinedione is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Antidiabetic Agents, Miscellaneous: AHFS 682092Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that Mifepristone (Korlym[®]) is classified as an antidiabetic agent, miscellaneous by the American Hospital Formulary Service. Mifepristone is a cortisol receptor blocker that the Food and Drug Administration (FDA)-approved to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes or glucose intolerance and have failed surgery or are not candidates for surgery.

The Endocrine Society Clinical Practice Guidelines for the Treatment of Cushing's Syndrome suggests administering mifepristone in patients with diabetes or glucose intolerance who are not surgical candidates or who have persistent disease after transsphenoidal selective adenomectomy.

There is insufficient evidence to support that one brand antidiabetic agent, miscellaneous is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand antidiabetic agent, miscellaneous is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Multivitamin Preparations: Prenatal Vitamins: AHFS 882800

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the prenatal vitamins that are included in this review are listed in Table 1 on page 1084. It should be noted that the products included in this review contain an extensive ingredient list, which can be found separately in the prescribing information. The term “prenatal vitamins” in Table 1 collectively refers to all active vitamin and mineral ingredients. Additional ingredients, including folic acid and iron, have been listed out separately. Many of the prenatal vitamins are available in a generic formulation, including products which contain omega-3 fatty acids. There have been no major changes in prescribing information, treatment guidelines, or clinical studies since the class was last reviewed.

There is insufficient evidence to support that one brand prenatal vitamin is safer or more efficacious than another within its given indication. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand products within the class reviewed are comparable to each other and to the generic products in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use.

No brand prenatal vitamin is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Immunomodulatory Agents used to treat Multiple Sclerosis: AHFS 922000

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that several immunomodulatory agents are Food and Drug Administration (FDA)-approved for the treatment of patients with multiple sclerosis (MS), including two agents

that have been approved since the last review. Alemtuzumab (Lemtrada®) is a CD52-directed cytolytic monoclonal antibody. Because of its safety risks, which include autoimmune conditions, stroke, and increased risk of malignancies, the use of alemtuzumab should generally be reserved for patients who have had inadequate response to two or more drugs indicated for the treatment of MS. Alemtuzumab is only available through a limited distribution program. Ocrelizumab (Ocrevus®) is a CD20-directed cytolytic antibody. The exact mechanism by which it exerts its therapeutic effect is not known. It binds to CD-20, a cell surface antigen present on pre-B and mature B lymphocytes, which results in antibody-dependent cellular cytotoxicity and complement-mediated lysis. Ocrelizumab was approved by the FDA in March 2017 for the treatment of both relapsing and primary progressive forms of MS. The ORATORIO trial evaluated ocrelizumab compared to placebo for the treatment of primary progressive MS. In this trial ocrelizumab demonstrated a statistically significant reduction in the percentage of patients who experienced confirmed disability progression (P=0.03). Ocrelizumab is the only agent within this class that is FDA-approved for the treatment of primary progressive MS. Additionally, daclizumab (Zinbryta®) was voluntarily withdrawn from the market in 2018 due to concerns about the drug's benefit/risk profile.

Current clinical guidelines generally recommend the immunomodulatory agents as first line agents. All available agents have been shown to decrease MRI lesion activity, prevent relapses, delay disease progression, and ultimately reduce disability from MS. The goals of MS therapy include slowing disease progression, reducing relapse rate and preventing or postponing long-term disability. Guidelines from the American Academy of Neurology (AAN) and the MS Coalition recommend that patient specific factors guide therapy. Specifically, the AAN guideline recommends alemtuzumab, fingolimod, or natalizumab for patients with highly-active relapsing remitting MS. Revised guidance from the Association of British Neurologists categorize therapies for relapsing remitting MS into two groups including agents of moderate efficacy (β-interferons, glatiramer acetate, teriflunomide, dimethyl fumarate, and fingolimod) and agents of high efficacy (alemtuzumab and natalizumab). They recommend starting with a moderate efficacy therapy given the improved safety profile. Clinical guidelines do not currently recommend therapy for individuals with primary progressive MS, though it should be noted that at the time the draft guidelines were published, the FDA had not issued a decision on ocrelizumab. Guidelines recommend the use of alemtuzumab in highly active MS; however, because of its safety profile, the use of alemtuzumab should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

The most frequently reported adverse events associated with IFNβ therapy are influenza-type symptoms, injection site reactions, headache, nausea, and musculoskeletal pain. Rare cases of hepatic toxicity have occurred in patients who were treated with IFN therapy. Therapy with IFNβ should be used cautiously in patients with depression or other mood disorders. Patients receiving glatiramer acetate therapy may experience a transient, self-limiting, post-injection systemic reaction (flushing, chest pain, palpitations, anxiety, dyspnea, throat constriction, and/or urticaria) immediately following drug administration. Ocrelizumab may cause infusion reactions and has been associated with an increased risk of infections and malignancies. Fingolimod has been associated with cardiac-related death and thus requires cardiac monitoring. It is contraindicated in patients with certain pre-existing cardiovascular conditions. Teriflunomide has boxed warnings regarding hepatotoxicity and its risk of teratogenicity. Dimethyl fumarate appears to have the

mildest side effect profile with its most common adverse events being flushing and gastrointestinal effects. Natalizumab increases the risk of progressive multifocal leukoencephalopathy (PML). When initiating and continuing treatment with natalizumab, physicians should consider whether the expected benefit is sufficient to offset this risk. Natalizumab is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the TOUCH® Prescribing Program because of the risk of PML. Because of the risks of autoimmune conditions, stroke, and increased risk of malignancies, alemtuzumab is also available only through a restricted program called the LEMTRADA REMS Program.

There is insufficient evidence to support that one brand immunomodulatory agent used to treat multiple sclerosis is safer or more efficacious than another within its given indication, with the exception of safety concerns associated with alemtuzumab use. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process. Because of its safety profile, the use of alemtuzumab should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

Therefore, all brand immunomodulatory agent used to treat multiple sclerosis, with the exception of alemtuzumab, within the class reviewed are comparable to each other and to the generic products in the class (if applicable) within their given indications and offer no significant clinical advantage over other alternatives in general use.

No brand immunomodulatory agent used to treat multiple sclerosis is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Alemtuzumab should not be placed in preferred status regardless of cost.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

Antigout Agents: AHFS 921600

Manufacturer comments on behalf of these products:

None

Dr. Bacon commented that the antigout agents that are included in this review are listed in Table 1 on page 1215. All products are currently available in a generic formulation, with the exception of febuxostat and pegloticase. This is the first review of this class.

The antigout agents are urate-lowering therapies with a variety of indications related to gout and hyperuricemia. Allopurinol is approved by the Food and Drug Administration (FDA) for the management of primary or secondary gout as well as management of calcium oxalate calculi in certain patients, and hyperuricemia in patients receiving chemotherapy. Colchicine is FDA-approved for treatment and prophylaxis of gout flares and treatment of familial Mediterranean fever. Probenecid is approved for the treatment of hyperuricemia in gout and as adjuvant therapy

with certain antibiotics. Febuxostat, pegloticase, and probenecid-colchicine are only FDA-approved for indications directly related to the treatment of gout.

The consensus guidelines for the treatment of gout recommend the use of a xanthine oxidase in patients requiring chronic pharmacotherapy. Preference for allopurinol or febuxostat is only given in the British Society for Rheumatology and European League Against Rheumatism guidelines which recommend the use of allopurinol first-line and use of febuxostat second-line. All guidelines recommend adjusting the dosing to reach a serum urate target of <6 mg/dL. Uricosuric agents such as probenecid are recommended in patients with a contraindication, inadequate response, or adverse reaction to xanthine oxidase inhibitors. The use of pegloticase is only discussed in the American College of Rheumatology and European League Against Rheumatism guidelines, both of which recommend it as last line for urate lowering in gout patients. For the treatment of acute gout attacks, colchicine is the recommended antigout agent along with nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroids. Colchicine is also discussed as appropriate therapy for gout attack prophylaxis.

Though there have been multiple head to head studies comparing agents within this class, there is limited evidence to support significant benefit with one agent over another when used for the same indication. There were a few trials that demonstrated a potential benefit with the use of febuxostat over allopurinol depending upon the dose; however, most of these trials utilized higher than FDA-approved doses of febuxostat. Additionally, the consensus guidelines do not reflect preference for febuxostat. Benefits from treatment with the antigout agents have been demonstrated in comparison to placebo and therefore support the use of these medications for their FDA-approved indications.

A clinical trial comparing the safety of allopurinol and febuxostat demonstrated an increased risk of death from any cause and death due to cardiovascular events in patients using febuxostat. After reviewing the safety data available for febuxostat, the FDA concluded that there is an increased risk of death with this agent compared to other antigout agents. The FDA deemed it appropriate to require a Boxed Warning and limit the use of febuxostat to those who have an inadequate response or are unable to tolerate allopurinol or in those for whom the use of allopurinol would not be advisable.

There is insufficient evidence to support that one brand antigout agent is more efficacious than another. Formulations without a generic alternative should be managed through the medical justification portion of the prior authorization process.

Therefore, all brand antigout agents within the class reviewed, with the exception of the febuxostat and pegloticase, are comparable to each other and to the generics in the class (if applicable) and offer no significant clinical advantage over other alternatives in general use. Febuxostat and pegloticase possess extensive adverse effect profiles compared to the other brands and generics in the class (if applicable) and should be managed through the medical justification portion of the prior authorization process.

No brand antigout agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost-effective products and possibly designate one or more preferred brands.

Febuxostat and pegloticase should not be placed in preferred status, regardless of cost.

There were no further discussions on the agents in this class. Chairperson Carter asked the P&T Committee members to mark their ballots.

6. RESULTS OF VOTING ANNOUNCED

The results of voting for each of the therapeutic classes were announced; all classes were approved as recommended. Results of voting are described in the Appendix to the minutes.

7. NEW BUSINESS

Governor Ivey has kicked off the Alabama Counts 2020 Census Initiative. The governor unveiled the Alabama Counts logo which will be included on the email signature of Agency employees. The census is tied to funding allocations of federal programs and number of government representatives.

This is Keisha Hawkin's last P&T meeting. She will be working with another department in the building. This is also Dr. Dawson's last meeting. We would like to thank both for their service to the Agency.

8. NEXT MEETING DATE

The next P&T Committee Meeting is scheduled for November 6, 2019 at the Medicaid Building in the Commissioner's Board Room.

9. ADJOURN

There being no further business, Dr. Heinze moved to adjourn and Dr. Newman seconded. The meeting adjourned at 10:21 a.m.

Appendix

RESULTS OF THE BALLOTING Alabama Medicaid Agency Pharmacy and Therapeutics Committee August 7, 2019

- A. Recommendation:** No brand first generation antihistamine is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Rouse, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director
Kathy Hull ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner
[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

- B. Recommendation:** No brand estrogen is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Rouse, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director
Kathy Hull ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner
[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

- C. Recommendation:** No brand alpha glucosidase inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

McRone, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Assistant Medical Director
John Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Deputy Commissioner
[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Commissioner

- D. Recommendation:** No brand amylinomimetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

McRone, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Assistant Medical Director
John Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Deputy Commissioner
[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Commissioner

- E. Recommendation:** No brand biguanide is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

McRone, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Assistant Medical Director
John Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Deputy Commissioner
[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Commissioner

- F. Recommendation:** No brand dipeptidyl peptidase-4 inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

McRone, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director
Kathy Kelly ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner
[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

- G. Recommendation:** No brand incretin mimetic is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

McRone, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director
Kathy Kelly ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner
[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

- H. Recommendation:** No brand insulin, with the exception of rapid-acting and long-acting insulin analogs, is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Alabama Medicaid should work with manufacturers on cost proposals so that at least one brand rapid-acting insulin analog is selected as a preferred agent.

Alabama Medicaid should work with manufacturers on cost proposals so that at least one brand long acting insulin analog is selected as a preferred agent.

Amendment: None

Vote: Unanimous to approve as recommended

McRone, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director
Kathy Kelly ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Deputy Commissioner

Commissioner

☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

- I. **Recommendation:** No brand meglitinide is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

McRae, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

Kathy Kelly ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

- J. **Recommendation:** No sodium-glucose cotransport 1 inhibitor is recommended for preferred status. Alabama Medicaid should continue to include AHFS Class 682017 in the Preferred Drug List screening process. If new prescription sodium-glucose cotransport 1 inhibitors are added, it is recommended that this class be re-reviewed.

Amendment: None

Vote: Unanimous to approve as recommended

McRae, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Assistant Medical Director

Kathy Kelly ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Deputy Commissioner

[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
Commissioner

- K. **Recommendation:** No brand sodium-glucose cotransport 2 inhibitor is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

McRae, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Assistant Medical Director

[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Deputy Commissioner

[Signature] ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Commissioner

- L. Recommendation:** No brand sulfonylurea is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Assistant Medical Director

[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Deputy Commissioner

[Signature] ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Commissioner

- M. Recommendation:** No brand thiazolidinedione is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Assistant Medical Director

[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Deputy Commissioner

[Signature] ☐ Approve ☐ Approve as amended ☐ Disapprove ☐ No action

Commissioner

- N. Recommendation:** No brand antidiabetic agent, miscellaneous is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Spence, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Assistant Medical Director
Kathy Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Deputy Commissioner
[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Commissioner

- O. Recommendation:** No brand prenatal vitamin is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Amendment: None

Vote: Unanimous to approve as recommended

M. Spence, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Assistant Medical Director
Kathy Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Deputy Commissioner
[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Commissioner

- P. Recommendation:** No brand immunomodulatory agent used to treat multiple sclerosis is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost effective products and possibly designate one or more preferred brands.

Alemtuzumab should not be placed in preferred status regardless of cost.

Amendment: None

Vote: Unanimous to approve as recommended

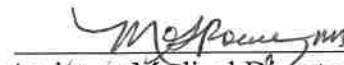


M. Spence, MD ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Assistant Medical Director
Kathy Hall ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Deputy Commissioner
[Signature] ☒ Approve ☐ Approve as amended ☐ Disapprove ☐ No action
 Commissioner

- Q. Recommendation:** No brand antigout agent is recommended for preferred status. Alabama Medicaid should accept cost proposals from manufacturers to determine the most cost-effective products and possibly designate one or more preferred brands.

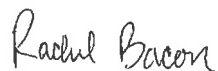
Febuxostat and pegloticase should not be placed in preferred status, regardless of cost.

Amendment: None

Vote: Unanimous to approve as recommended

	<input checked="" type="checkbox"/> Approve <input type="checkbox"/> Approve as amended <input type="checkbox"/> Disapprove <input type="checkbox"/> No action
Assistant Medical Director	
	<input checked="" type="checkbox"/> Approve <input type="checkbox"/> Approve as amended <input type="checkbox"/> Disapprove <input type="checkbox"/> No action
Deputy Commissioner	
	<input checked="" type="checkbox"/> Approve <input type="checkbox"/> Approve as amended <input type="checkbox"/> Disapprove <input type="checkbox"/> No action
Commissioner	

Respectfully submitted,



Rachel Bacon, Pharm.D.

August 12, 2019

Date